Exhibit A
Part 1 of 3

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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IN RE: PHARMACEUTICAL	)	MDL NO. 1456
INDUSTRY AVERAGE WHOLESALE	)	CIVIL ACTION
PRICE LITIGATION	)	01-CV-12257-PBS
THIS DOCUMENT RELATES TO	)	
U.S. ex rel. Ven-a-Care of	)	Judge Patti B. Saris
the Florida Keys, Inc.	)	
v.	)	Chief Magistrate
Abbott Laboratories, Inc.,	)	Judge Marianne B.
No. 06-CV-11337-PBS	)	Bowler

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Videotaped deposition of STEPHEN W. SCHONDELMEYER, PHARM.D., PH.D.

Volume I

Washington, D.C.

Wednesday, February 25, 2009

9:00 a.m.

Page 70

A. It was essentially the same parties that hired me for that June 2008 report. It's a group of pharmacists that are providers to the Medi-Cal program.

Q. What's the name of that group of pharmacists?

A. Again, I'd have to look it up. I don't recall.

Q. Did your report last week reach substantially different conclusions than your report in June of 2008 reached?

A. Well, the situation and the facts were different. So there are some differences. But I think the same basic premises are present.

Q. How did the facts differ?

A. Well, both of these had issues with respect to how the Medi-Cal program and the state of California directed the Medi-Cal program to pay providers for prescription drugs. And the case last year involved the state budget directing the Medi-Cal program to cut payments to providers by 10 percent across the board and again, other things that are

Page 71

described thoroughly in that report.

The most recent case -- and it's my understanding, again, I don't follow all the legal side of it. I do the legal expert pharmaceutical market analysis. My understanding is preliminary injunction was issued or an injunction was issued that stayed that action by the state and subsequent to that the state of California legislature passed a budget that involved a 5 percent cut in the payments to providers across the board.

So it differed substantially by the percentage of the cut. But it was, again, across the board for all payments for pharmaceuticals under Medi-Cal for outpatient services.

Q. What was the context of your 2009 report, the one that you filed just last week?

A. I just described that.

Q. What were you asked to opine about in the report that you filed last week? What opinion were you asked for?

A. The opinion was what would be the impact on providers being in this case pharmacies and/or

Page 72

physicians or those who are paid for prescription drugs on an outpatient basis and what would the impact be on Medi-Cal recipients and Medi-Cal of the budget cut that had been legislated.

Q. What did you conclude with respect to the 5 percent reduction in payments to providers under Medi-Cal?

A. Well, my conclusions are stated in detail in that report. I wouldn't want to attempt to cite for you all of that report here.

Q. Can you characterize your conclusions in any way?

A. I could characterize it, but I would qualify that you need to refer to the entire report to understand the conclusions that I characterize. I believe in that report I characterized that a cut would in some cases result in paying the pharmacy below their actual costs for the drug product and in some cases below their actual cost of dispensing for the drug product and that such behavior could or such payment policy could result in pharmacies either refusing to provide prescription drugs under the

Page 73

Medi-Cal program, certain prescription drugs, or to participate in general, and changes in that could affect access of patients in California to outpatient prescription drugs.

Q. Could you have rendered such an opinion in this case?

A. I wasn't asked to. Again -- I don't know what you mean by such an opinion. Do you mean the same conclusion? Probably not. They have different facts.

Q. Sure. I understand. You understand that this case involves an allegation that payments to providers and pharmacies were over that which was intended by the Medicaid and Medicare program? Is that a fair description of your understanding of the case?

MS. BROOKER: Objection, form.

MR. COOK: Yeah. That is two questions. Let me ask it better.

BY MR. COOK:

Q. Is it your understanding of the case that the government alleges that providers and pharmacies

Page 118

but does describe what you assert did happen? "In addition, the financial incentives created by this profitability played a large and problematic role in prescribing decisions, that is, prescribers responded to these high margins by tending towards administering more drugs and more expensive drugs than might be medically necessary or optimal for the health of the patient."

A. You read a statement in paragraph 166 that I believe to be true in the context of the rest of the discussion presented in that paragraph and the rest of my report. I don't think you can take the statement in isolation, though.

Q. But I am correct that you are stating what did happen, not what might have happened, correct?

MR. BREEN: Objection, form.

A. Take the statement at its face value.

Q. Will you agree with me that the statement asserts what did happen, not when might have happened?

MS. BROOKER: Objection, form.

A. I think it encompasses both, things that did happen and things that also might have happened.

Page 119

Q. You mentioned Medicaid and your report relates to how Medicaid paid for various drugs, correct?

A. My report addresses Medicaid and the payment for prescription drugs.

Q. The estimated acquisition cost regulation that governed how Medicaid programs set up their payment formula. Would you agree with me that that regulation didn't change at all between 1991 and 2001?

A. I'm not sure I understand your question. What reg -- can you show me what regulation you're referring to?

Q. Well, let me show you in your report the regulation that you cite. It's on page 29, paragraph 52. You cite 42 C.F.R. Section 447.301, the October 1, 2001 edition of the Code of Federal Regulations. Do you see that?

A. I see that particular reference.

Q. Is it your understanding that that regulation as it existed in 2001 was the same regulation between 1991 and 2001?

A. I'd have to look back. There were a variety of changes in the regulation that occurred. But the definition of estimated acquisition cost to the best of my knowledge did not change.

Page 120

Q. Over what period did the definition of estimated acquisition cost remain the same?

A. I believe that the stated explanation of estimated acquisition cost has been substantially the same since 1977 to the present in a broad sense. The explanation I believe in paragraph 53 of page 30 in Exhibit 1, I think we're still in, describes the intended definition of estimated acquisition cost dates as far back as 1977 as described in an HHS document titled "Limitation on payment" -- probably an "of" rather than an "or" -- "reimbursement for drugs: Estimated acquisition cost."

It goes on to describe the intent of the regulation was for each state to pay estimated acquisition costs, which was to be a cost as close as feasible to the price generally and currently paid by providers. And that similar statement and policy has been in effect since that time.

Q. I'd like to turn your attention to paragraph 52, the second sentence that bleeds over for a couple words onto page 30. And I'll read it for the record and we'll be put it up on the screen. "The estimated acquisition cost was developed as a way to simplify payment for prescriptions in a manner that was consistent with the Medicaid program's intent to pay the actual acquisition cost for a given prescription drug or as close to the actual acquisition cost as is feasible." Do you see that?

Page 121

A. I see that statement.

Q. And on what do you base your opinion that it was the Medicaid's program's intent to pay the actual acquisition cost for a given prescription drug or as close to the actual acquisition cost as is feasible?

A. That was from statements made by the government in program memoranda, in final rules and the other documents that I've cited later down in paragraph 53 --

Q. Could you point me to the --

A. -- cite sources.

MS. BROOKER: I'm sorry. Dr.

Page 122

Schondelmeyer -- can you let him finish his answer please, Chris?

Q. Could you point me to the specific bases for that understanding as reflected in your report? And I suppose we can start with 42 C.F.R. Section 447.301, which you site just above that, right?

A. I don't recall that. If you go down to paragraph 53 there is -- I think the third sentence in paragraph 53. It says "the HHS memo to state Medicaid directors stated 'the intention of the final Medicaid regulations on drug reimbursement is to have each state's estimated acquisition cost as close as feasible to the price generally and currently paid by the provider. The states are therefore expected to set their ingredient cost levels as close as possible to actual acquisition costs'" and that the reference for that is cited as HHS action transmittal and it gives a Bates number and dated December 13th 1977.

Q. Keep your finger on that page but turn to paragraph 228 on page 103 of your report in the summary section. The summary section summarizes the opinions that you're expressing in this report,

Page 123

correct?

A. It's a summary. It certainly isn't all the opinions, but it's a summary.

Q. But it's fair to say that you picked out the most important aspects of the preceding 102 pages to include in your summary, right?

MS. BROOKER: Objection, form.

A. It's an overview of the conclusions. The report as a whole stands.

Q. The very first sentence of your summary reads "The Medicaid drug reimbursement system is based upon the consistently stated intention of reimbursing for drug products at their actual price, that is, a price 'as close as feasible to the price generally and currently paid by the provider,' a concept referred to in the Medicaid program regulations and policies as 'estimated acquisition cost.'" Did I read that correctly?

A. I believe you did. I didn't follow every word, but I believe it was correct.

Q. The concept that you state in the very first sentence of your summary is the same concept as

Page 124

you set forth for the first time in paragraph 52 of your report talking about the Medicaid program's intent, correct?

A. I'd have to look back if that's the first place I cited that. I wouldn't want to say that's the first place I cited that.

Q. But you would agree with me that --

A. Those are related. I don't know what you're asking.

Q. I'm just trying to establish -- and maybe we can get to it very quickly. Would you agree with me that your conclusion regarding the Medicaid program's intent to pay actual acquisition cost for a given drug or as close to the actual acquisition cost as is feasible is an important basis for your ultimate conclusions and opinions?

MR. BREEN: Objection, form.

A. I believe this statement reflects the intention of the Medicaid program and what they expected in terms of their reimbursement system and how it was to operate and how payors, providers, manufacturers and others were to interact with and

Page 125

facilitate the payment that accomplished that goal.

Q. And when you conclude that Medicaid programs paid too much for Abbott drugs between 1991 and 2001, or at least those in the complaint, it is that intention by the Medicaid program against which you are measuring the actual payment, correct?

A. Well, I think this is an underlying principle that states the government's expectation of what estimated acquisition cost should accomplish. Although there are other factors that influence it, this is one component of that, but not everything. As I describe in detail in other parts of the report, the payment under Medicaid is the lower of estimated acquisition cost plus a dispensing fee, or the federal upper limit plus a dispensing fee, or if the state has state maximum allowable cost limits set plus a dispensing fee, or the pharmacy's usual and customary charge for a prescription.

And I think the reporting of inflated prices to the price databases could influence other aspects in addition to the estimated acquisition cost. But this is one important component, yes.

Page 138

two sections is that the federal program expected states to comply with that and that if states did not those states would be viewed out of compliance with the federal directives.

Q. Again, we'll get to the Federal Government in a minute. But I'm simply trying to find out whether I need to ask you more questions about whether or not you are purporting to give testimony about the intent of the various state Medicaid programs. And so I'll ask you directly again.

Are you giving testimony about what the intent was of any of the various individual state Medicaid programs?

MS. BROOKER: Objection, form.

MR. BREEN: Objection, form.

A. To the best of my knowledge, states intended to follow the federal directives so that they could qualify for the federal cost sharing. That following the federal directives included following the statements that I've pointed you to that are in paragraph 534. So in that context I do believe the states intended to follow all of the directives from

Page 139

the federal government so that they would qualify for the cost sharing. And I believe it was the federal program's directive that they all were expected to set their ingredient cost levels as close as possible to actual acquisition cost as stated in the directive memo that I pointed out to you.

Q. Your testimony and your statements in the report about the Medicaid program's intent, can you tell me is that an opinion you're asserting, is that an assumption that you've made, or is that a conclusion that you've drawn from reviewing evidence, or is it none of those?

MS. BROOKER: Objection, form.

A. The information presented here, first of all, is based upon the sources described which are matters of public record. And I've reviewed the public record with respect to this program and the policy and the detailed ways in which it's implemented. I've tracked and monitored and examined in various ways evaluated, advised various Medicaid programs in the federal government and Medicaid over 30 years. So this draws upon both what's stated in

Page 140

policy documents. It draws upon my experience in working with Medicaid at the federal level and Medicaid at state levels. And this represents an opinion that I believe to be true based on all of those factors.

Q. I'll ask you a series of yes or no questions and I'll ask if you can simply say yes, no, or I can't answer it yes or no. The statement in paragraph 52 regarding the Medicaid program's intent, is that statement an assumption that you have made?

MR. BREEN: Objection, form.

A. I believe this to be a true statement. I can't answer that yes or no.

Q. Have you assumed it to be true or do you know it to be true?

MR. BREEN: Objection, form.

A. I know this to be true.

Q. Do you know this to be true based upon personal knowledge or based upon people you've spoken to and things you've read?

A. All of the above.

MS. BROOKER: Chris, at an appropriate time

Page 141

can we take a break whenever you want?

MR. COOK: Yeah, let's take a break.

MS. BROOKER: You want to do it now?

MR. COOK: Yeah.

THE VIDEOGRAPHER: Off the record at 11:50.

(Recess.)

THE VIDEOGRAPHER: On the record at 12:03.

BY MR. COOK:

Q. Dr. Schondelmeyer, I'd like to turn your attention to paragraph 228 of your report. And this is the first paragraph of your summary at the end of your report. We already looked at the first sentence of paragraph 228 and that is your statement about Medicaid intending to reimburse for drug products at their actual price. Do you see that?

A. I see the paragraph 228.

Q. Do you see that in the first sentence you state, or you characterize Medicaid's "stated intention of reimbursing for drug products at their actual price"?

A. Yes.

Q. The second sentence relates to Medicare

Page 158

MS. BROOKER: Objection, form.
A. I'm answering the question. I did use the word just fine. And by that I meant accomplishing the stated intent of the program. So I think ASP would have moved closer toward accomplishing the stated intent of the program to pay as close as feasible to actual acquisition cost.
Q. So let's take Medicare. Medicare from 1998 through 2001 paid 95 percent of the AWP for Medicare Part B administered drugs, correct?
A. In general, with exceptions as we've noted.
Q. What exceptions?
A. With exceptions? I'd have to go back and look up the regulatory exceptions as I've told you several times today I haven't memorized all of those.
Q. There's a regulatory exception to the Medicare Part B payment formula between 1998 and 2001; is that what you're telling me?
A. I don't recall specifically. There may be. Often there were, over time, various minor drugs in exceptions. In general it was 95 percent of AWP.
Q. Is it your testimony that the system would

Page 159

have worked just fine if Medicare Part B had paid 95 percent of ASP between '98 and 2001?
MS. BROOKER: Objection, form.
A. No. That's not my testimony at all. I think the Congress moved toward 95 percent of AWP because they realized that some payors were paying less than AWP and realizing that they weren't getting complete and accurate information from the manufacturers that represented prices generally and currently being paid, they made attempts in their reimbursement system to adjust for that. But again, they may not have even adopted the 95 percent of AWP had the prices generally and currently being paid been reported prior to that time. So that policy may not have even been enacted by Congress.
Q. So what your telling me is that if manufacturers had reported prices other than the prices that they did report, a result might have been a change in the system?
A. Not just other than. If they had reported accurate prices that were verifiable and the market recognized as prices generally and currently being

Page 160

paid, there might have been a different payment system later, yes. Or they would have stayed with the same payment system because they said our intent is to pay the price actually generally and currently paid by providers and if they had evidence that that's what was being paid, the intent of the program would have been accomplished.
Q. So are you moving away from your belief that with accurate prices in the system and average prices being published in Red Book the system would have worked just fine?
MS. BROOKER: Objection, form.
A. I don't understand why you say moving away from my belief. I'm saying that if the government felt confident that accurate prices were being reported they may not have changed their policy over time. Changes in the policy occurred over time because, as the government became aware that various providers were paying different prices and there were various reasons for those prices in the marketplace, they attempted to make what corrections they could. But they still didn't have accurate prices from

Page 161

manufacturers. Truthful prices.
Q. Can you tell me what the system would have been if Red Book had been reporting empirical averages of wholesale prices --
MS. BROOKER: Objection, form.
Q. -- between 1991 and 2001?
A. Well, you said empirical averages of wholesale prices. I would qualify that because that term doesn't have a specific meaning to me. If it was actual prices currently and generally being paid I could tell you. If it's wholesale prices by some other definition, it may be a different conclusion.
Q. You're familiar with the definition that Judge Saris gave to average wholesale price in this case, correct?
MS. BROOKER: Objection, form.
A. I recall seeing her definition. I believe I commented on it at some point.
Q. What do you understand Judge Saris' definition of average wholesale price to be?
MS. BROOKER: Objection, form.
A. I believe -- again, we have to -- obviously

Page 162

I'm not going to attempt to overly restate her position. But my understanding is that average wholesale price has the plain meaning of an average wholesale price. That was what she felt it was intended to be. That isn't the prices reported.

Q. Do you know where in your report you describe Judge Saris' definition of average wholesale price?

A. I don't, but I could look.

Q. Can you tell me whether the system would have worked just fine if the average wholesale prices reported in Red Book and other compendia had been average wholesale price as defined by Judge Saris?

MS. BROOKER: Objection, form.

A. I think back over time if the prices being reported as average wholesale prices would have been prices generally and currently paid in the market, which I think is consistent with Judge Saris' expectation, I think the payment system would have been accomplishing its intent, which is what I meant by just fine, that it accomplished its intent of paying a price generally and currently paid that's as

Page 163

close as feasible to actual price.

MS. BROOKER: Paragraph 46.

MR. COOK: Thank-you.

Q. Turn to paragraph 46. You refer in paragraph 46 to Judge Saris having examined the meaning of the term AWP in the Medicare context and determined that the term to be given its plain meaning in accordance with established principles of statutory construction. Did I read that correctly?

A. Actually, I haven't found that. This is paragraph 46 of which document?

Q. Paragraph 46 of your report in Exhibit 1.

MS. BROOKER: Not page.

Q. Paragraph 46.

A. I'm on paragraph 46.

Q. The third sentence.

A. Oh, I see, it's in the middle. Okay, I see it now, yes.

Q. All right what is your understanding of the meaning of average wholesale price as defined by Judge Saris?

A. I answered that previously, and I state

Page 164

here what that is. That it has the plain meaning in accordance with established principles of statutory construction. That is that it's an average of the wholesale prices, meaning -- and price meaning an actual price being paid in the market, a transaction price, not a list or a fictitious price.

Q. If the average wholesale prices used by the Medicare and the Medicaid programs between 1991 and 2001 had universally fit Judge Saris' definition, are you able to testify that those programs would have continued as they were and simply paid less money?

MS. BROOKER: Objection, form.

A. Well, if they used those prices and the prices reported by the manufacturers that created the databases that Medicare and Medicaid relied upon had been prices generally and currently paid in the market that were as close as feasible to actual acquisition cost, I believe with respect to at least drug product cost payment that the payment process by Medicare and Medicaid wouldn't have changed in ways that it did and would have resulted in lower payments for those drugs.

Q. Only on the drug ingredient cost portion

Page 165

though, correct?

A. Well, that's the only part that we're evaluating here. This isn't about other aspects.

Q. You don't consider what effect that might have had on the dispensing fee component of the payment?

MS. BROOKER: Objection, form.

A. That's a separate consideration and that could be evaluated.

Q. So you haven't considered in any way what the effect of lowering drug ingredient cost would have on dispensing fees in the Medicare and Medicaid programs?

MR. BREEN: Objection, form.

A. Not in the context of this case.

Q. So you're coming here to testify about lowering the drug ingredient cost for Medicare and Medicaid between 1991 and 2001, and you're not in any way considering what impact that might have had on the dispensing fee? Do I have that correct?

MS. BROOKER: Objection, form.

A. I have considered that. I don't think one

Page 186

did.

Q. And so Myers and Stauffer did a report for that commission with respect to dispensing costs and acquisition costs? Do I have that correct?

A. For the Minnesota Medicaid program with direction from the commission.

Q. Did Myers and Stauffer reach any conclusions about what it cost home infusion pharmacies to dispense products in Minnesota?

A. I believe they just reported descriptive information on that and didn't address specific conclusions. It wasn't the main purpose of the report.

Q. Did Myers and Stauffer quantify the difference in the cost of dispensing for home IV pharmacies as opposed to retail pharmacies in that report?

A. Again, I believe they reported descriptively that. But again, it wasn't the main focus of the report, so --

Q. What was the description that Myers and Stauffer provided when comparing the cost to dispense

Page 187

between home IV pharmacies and retail pharmacies in that report?

A. Well, I don't recall the specifics. But in general the home IV pharmacies did have a higher cost of dispensing than the typical retail community pharmacies. But I don't recall the detail or the specific quantity.

Q. Did the commission that you chaired result in any changes in the manner in which Minnesota Medicaid paid for pharmaceutical products?

A. The commission primarily addressed issues subsequent to the Deficit Reduction Act that was passed and certain provisions of that were actually put on hold due to an injunction. And so most of the issues we addressed became moot because of that injunction.

Q. If the injunction had not been issued what did the commission recommend that Minnesota Medicaid do in light of the Deficit Reduction Act?

A. Oh, I'd have to look back. It's been a while since I've done that. I have to look back at the detail of that report.

Page 188

Q. Can you characterize it in any way whatsoever?

A. Well, the commission was looking at the impact on providers of cutting their payments for ingredient costs below the actual acquisition cost, which is a different circumstance than what we're describing here where pharmacies got paid above the actual acquisition cost. So we looked at and just comment upon that it wouldn't be reasonable for businesses since pharmacies in home -- in this case pharmacies was the primary focus -- and providers to the Medicaid program are private businesses. It wouldn't be reasonable for them to operate at below cost in the marketplace.

And if indeed the Deficit Reduction Act resulted in payments that were below cost for certain products that those pharmacies may either not dispense those products or may drop out of the Medicaid program.

Q. So in this particular commission you compared the ingredient cost before the DRA to the ingredient cost after the DRA without looking at the

Page 189

adequacy of the dispensing fee; do I have that correct?

A. We attempted to model what the ingredient cost would be after the DRA since it hadn't been implemented and it involved average manufacturer's prices being reported by manufacturers under a new definition than the one that existed previously for which nobody had ever seen data. So we tried to model what those prices might look like from other data and tried to identify what the impact would be on product costs, and that if in fact it resulted in a product cost below what pharmacies actually paid that the primary providers in the Medicaid program, if it resulted in a product cost below what pharmacies actually paid, we commented that that would affect access.

Q. Who is Cody Wiberg?

A. Cody Wiberg is a pharmacist in Minnesota. He currently is the executive director of the Minnesota board of pharmacy.

Q. What was his prior position?

A. Prior to that he was a pharmacy program

Page 190

manager of some type within the Medicaid program in Minnesota.

Q. And when was he the pharmacy administrator for Minnesota Medicaid?

A. He wasn't the administrator. He was a manager. Not the principal administrator. I don't recall when he finished. From the late '90s until sometime maybe four or five years later. He was not in that position when I chaired the commission we're talking about.

Q. Are you aware that Minnesota Medicaid has MACs, M-A-Cs, established for a number of the products that it reimbursed during the time period 1991 to 2001?

A. Yes, I am.

Q. How did Minnesota Medicaid set those MAC prices?

A. That's somewhat of a mystery perhaps sometimes, although they had a procedure defined and they would check with some pharmacists in the state to identify. But not on a very systematic basis. It was kind of a network of friends which -- you know, it

Page 191

wasn't as systematic as other states I've seen perhaps.

Q. Is it your testimony as an expert that Minnesota Medicaid intended to set MAC prices as close as possible to the actual acquisition cost for pharmacies of those products that they were MAC'ing?

A. I think MAC prices are one part of an overall reimbursement formula. And there are a variety of factors that go into setting MAC prices. I think MAC prices are intended to set an upper limit on the payment for prescription drugs in the Medicaid program. And MAC prices first of all are used in products that are generics that have therapeutic equivalents and not only multiple purchasers but multiple manufacturers selling therapeutically equivalent products and there may be different prices across those different manufacturers.

And so in setting the MAC rate, this upper limit for payment. It's not the criteria -- they don't pay MAC automatically. It's one of a criteria of several other things in a lower-of criteria. But it's setting the upper limit. I believe that

Page 192

Minnesota and other states when they set MAC rates want to set a maximum allowable cost for a given generic product taking into account the prices across different manufacturers and across different providers for the same manufacturer as well as across different providers for different manufacturers to represent and identify an upper limit such that pharmacies in the state could generally and currently purchase products at that price, but not the lowest possible price.

Q. Was it your understanding that in setting MACs the Minnesota Medicaid program intentionally created a spread between actual acquisition cost and the MAC?

A. I'm aware that MAC programs sometimes would identify the lowest price and multiply it times a multiplier -- for example, 150 percent -- so that it would create a range to assure that most pharmacies could generally and currently purchase products at that price.

MR. COOK: Could you read the question back, please?

(Whereupon, the requested portion was read

Page 193

by the reporter.)

BY MR. COOK:

Q. Can you answer that question yes or no?

MS. BROOKER: Objection, form.

A. I would have to ask what you mean by spread. I defined it as I intended. And that was it multiplied 150 percent times the lowest price they found. It creates a type of spread. But it was with the intention of setting a price such that they could reasonably expect that pharmacies could generally and currently purchase the product at or below that price.

If you have a different meaning of spread or a different context and want to clarify that, I'd be glad to try to address it.

Q. Was it your understanding that in paying the ingredient cost portion of its drug reimbursement in the 1990s the Minnesota Medicaid program intended to pay a dollar amount greater than actual acquisition cost?

A. For dispensing fees or for ingredient cost or --

MR. COOK: Could you read the question

Page 194

again?
(Whereupon, the requested portion was read by the reporter.)
A. Again, with generics there are different providers in the marketplace. And I think they intended to pay greater than the lowest price in the market at times. What the Medicaid program intended within the scope of their state plan beyond that I think is a matter of evaluation in terms of the state plan and the federal regulations.
BY MR. COOK:
Q. Is it your understanding that the Medicaid program in Minnesota in the 1990s intended to pay the pharmacies approximately 8 to $10 more than their actual acquisition cost in setting their ingredient cost?
A. There may be Medicaid programs -- Cody may have made such a comment. Cody sometimes expressed views and opinions that weren't necessarily the official opinion of the state Medicaid program.
MR. COOK: Could you read my question again?

Page 195

(Whereupon, the requested portion was read by the reporter.)
A. I've seen no written document stating that from the state of Minnesota Medicaid program. I've seen no statute or policy advocating that from the state of Minnesota. You know, given official sources that I would normally look at and rely upon, I've seen no evidence of that.
BY MR. COOK:
Q. Have you read Cody Wiberg's deposition in this case?
A. I did read his deposition.
Q. So when I asked you that question and you said you had seen no evidence of it you didn't bother listing off the testimony of the pharmacy administrator in Minnesota, right?
MS. BROOKER: Objection, form.
A. I listed off the sources that I would refer to to see what the policy of Minnesota Medicaid is. In general, while Cody had some role over policy that was not to the best of my understanding within the scope of his authority to make such a policy.

Page 196

Q. Is it your testimony that you are ascribing an intent to Minnesota Medicaid different than Mr. Wiberg ascribed to it?
MS. BROOKER: Objection.
A. I haven't offered an opinion on what Minnesota Medicaid's intent per se was. You've offered to me what Cody Wiberg's opinion was on that. And my comment is that I don't see in Minnesota documents statements that support that.
Q. Did Minnesota Medicaid intend to pay more than acquisition cost in the ingredient cost portion of their drug reimbursement between 1990 and 2001?
MR. BREEN: Objection, form.
A. I've seen no document from the state of Minnesota saying that they intended to do that. I did read the deposition of Cody Wiberg and see what he said as an individual. But in working with Medicaid programs in general and with the state of Minnesota, I'm not aware of any document that says that that was their intent, an official document that holds the weight of policy.
MR. COOK: Could you read my question back,

Page 197

please?
(Whereupon, the requested portion was read by the reporter.)
MS. BROOKER: Objection, asked and answered.
BY MR. COOK:
Q. Can you answer that question yes or no?
MR. BREEN: Objection, form.
A. I can't answer that yes or no. I can answer it with a qualification, as I've done.
Q. So on page 29 of your report you can opine on the Medicaid program's intent to pay actual acquisition cost, but to be real clear you are unable to opine on what the intent was of the Medicaid program in Minnesota, correct?
MS. BROOKER: Objection.
MR. BREEN: Objection, form.
A. No. That's not correct. I think the statement on -- if you'll permit me to go there. The statement on page 29, paragraph 52 that you're referring to is again the one that I said is the federal Medicaid's intent. And as I pointed out on

Page 198

paragraph 53 on the next page, that that's the expectation of the federal program that the states will set their ingredient cost levels as close as possible to actual acquisition cost. And I believe that that is the intent of the Medicaid program in Minnesota as well.

And I have not seen official documents from the state in writing that suggest otherwise, notwithstanding the comments in deposition of Cody Wiberg. But that isn't an official document or doesn't hold the weight of policy.

Q. Earlier on today when you were describing how it was that you can testify what Medicaid expected and what Medicaid intended, you referred to conversations you had had with officials at various Medicaid and Medicare programs. Do you recall that testimony?

A. I recall something to that effect. I don't know if it was exactly that term.

Q. So now you're no longer willing to rely upon conversations with officials at Medicare and Medicaid in determining what Medicare and Medicaid

Page 199

intended? Do I have that correct?

MS. BROOKER: Objection, form.

A. No, you don't have it correct. I do take into account comments of officials. But I also compare those against the official documents and the official statutes, regulations and policies issued by federal Medicaid and state plans of state Medicaid programs, and I give those more weight than the comment of an individual that's not backed up by those documents.

Q. So in reviewing statements and sworn testimony in preparation for your testimony today you weighed the various testimony and decided which was more credible and which was less credible? Do I have that correct?

MS. BROOKER: Objection, form.

A. I would phrase it more that I identified what are the statutes, regulations, written policies of the federal and state Medicaid programs. And then when I read depositions or comments of various individuals I compared them, weighed them, against the official formal written policies and documents. And

Page 200

when I have a difference between those I do give deference to the official formal written policies versus the comment of an individual. Yes, I do give deference to official policies.

Q. Are you offering an opinion on the meaning of federal statutes and regulations that you reviewed in preparation for your testimony here today?

A. I don't understand what you mean.

Q. Well, you're telling me that when you testify or give an opinion about what Medicaid intended you're basing that upon regulations and official documents from the Medicaid program; do I have that correct?

A. On --

MS. BROOKER: Objection, form. Sorry. Go ahead.

A. I'm basing it on written statutes, regulations, policy memorandum and other documents and I've quoted in here sources that I am relying upon that are official documents and have consistently reported this same information over time.

Q. What expertise do you have to interpret for

Page 201

this jury statutes, regulations and official documents?

A. Well, I don't do so as a lawyer in the legal sense. However, my master's degree is in public administration and public policy from Ohio State University. And that master's program, the core of that was based on three major courses. One was the policy formulation. One was policy implementation. And one was policy evaluation.

And as a part of that master's program in addition to the methods of each of those processes we had to pick a particular piece of legislation and do a complete legislative history and documentation and interpretation of what were the factors involved in the formulation of that policy, what were the factors involved in implementation of that policy and what were the factors involved in evaluation of that policy, and to what degree did the reasons it was brought about and the ways it was implemented have concurrence with what actually occurred at the end.

I looked at -- I believe it was Public Law 93641, which was -- I believe that was a health

Page 290

an understanding of how it was that Medicare Part B paid for the drugs listed in Exhibit 547 when they were administered to a Medicaid beneficiary on an outpatient basis between 1992 and 1998?

A. I've read this and it does refer to the lower of the estimated acquisition cost or the national average wholesale price of the drug. The estimated acquisition cost it describes in the regulation is to be determined based on surveys of actual invoice prices paid for the drug.

Q. My question to you is what percentage of the claims submitted to Medicare Part B for drugs in this case between 1992 and 1997 were paid based upon estimated acquisition cost and what percentage were paid based upon the national average wholesale price?

A. I don't know that specifically. One could assess that. With a data set of claims that were paid and with a data set that had the historical prices in the national average wholesale price database, you could assess which ones were paid at that national average wholesale price or ones that were paid on a different basis. So one could assess that and that is

Page 291

measurable. I wasn't asked to do damages or estimate the quantity or a value of claims paid on a specific basis.

Q. Were claims paid by Medicare Part B based upon the national average wholesale price between 1992 and 1997?

A. I believe there are and would have been some based on this approach.

Q. Were claims paid by Medicare Part B between 1992 and 1998 based upon the estimated acquisition cost as described in this regulation?

A. They may or may not have been. It's my understanding that the carriers that were to implement this had some difficulty in doing invoice surveys and even invoices may or may not have reported prices actually, you know, currently and generally being paid by providers. Sometimes invoices carry a list price, i.e. the average wholesale price or the wholesale acquisition cost, which isn't necessarily the price generally and currently being paid. It's kind of a list price even on the invoice and then sometimes there are off invoice discounts.

Page 292

Earlier I referred to IMS does -- is a data collection service that largely collects information from pharmacies, hospitals, wholesalers and then provides information back to pharmaceutical companies, used for market intelligence, including pricing issues. But the invoice data they collect is invoice data before discounts are taken. And so it isn't always a reflection of the prices actually generally and currently being paid in the market.

MR. BREEN: Chris, are we at a point where we can take a break?

MR. COOK: That would be a great idea.

MR. BREEN: Are you done with this section?

MR. COOK: We can come back to it. This is a good place for a break.

THE VIDEOGRAPHER: Off the record at 4:02.

(Recess.)

(Exhibit Abbott Schondelmeyer 004 and Exhibit Abbott Schondelmeyer 005 were marked for identification.)

THE VIDEOGRAPHER: On the record at 4:13.

BY MR. COOK:

Page 293

Q. Mr. Schondelmeyer, I will hand you what I've asked the court reporter to mark as Exhibits 4 and Exhibit 5. And while you look at those, for the record, Exhibit 4 is a June 2002 report by Myers and Stauffer entitled "Study of Medi-Cal pharmacy reimbursement." Exhibit 5 is a report prepared by you dated June 2008 entitled "Impact of 10 percent fee for service payment reductions on Medi-Cal beneficiaries and pharmacies."

Now, turning your attention first back to Exhibit 3 -- and we'll be looking at Exhibits 3, 4 and 5 in conjunction -- Exhibit 3 is the December 2007 Myers and Stauffer report on a survey of dispensing and acquisition costs of pharmaceuticals in the state of California. And if you turn where we were before on pages 6 and 7 of Exhibit 3, we were in the process of summarizing the conclusions of Myers and Stauffer in this December 2007 report.

Now, starting with the section entitled "dispensing cost," would you agree with me that Myers and Stauffer concluded the state-wide average or mean cost of dispensing weighted by Medi-Cal volume was

Page 294

$10.81 per prescription?
A. That's on page 6? Is that the one you're referring to?
Q. Yes, sir. The bolded language under dispensing cost.
A. What you've said is a close paraphrase of what their conclusion appears to be.
Q. And you've incorporated that conclusion into reports that you've prepared, including specifically Exhibit 5, the June 3, 2008 report, correct?
A. I discuss that conclusion and address comments and criticisms of their method and alternative conclusions.
Q. Do you have any reason to believe that the $10.81 per prescription cost that Myers and Stauffer found in December 2007 overstated the cost to dispense pharmaceuticals in California?
A. Well, I believe it's an average or a mean cost of dispensing as they defined weighted on Medi-Cal volume. It may overstate for some specific pharmacies their cost of dispensing. I believe there

Page 295

were pharmacies with cost of dispensing that appeared to be as low as 4 or $5 and some with costs of dispensing that went up to 50 or $60.
Q. But you would consider the Myers and Stauffer survey and analysis to be accurate, correct?
A. No. I didn't say that. I said I wrote an analysis and critique of their methods and alternative conclusions based on that critique. I believe they provided useful information, but it's not completely accurate.
Q. What inaccuracies specifically can you identify in the Myers and Stauffer conclusion about the cost to dispense drugs in California?
A. I can't off the top of my head. I could refer you to the report that I produced in the California Exhibit 5.
Q. The --
A. And there we specify the criticisms. It lists the criticisms I have and gives a detailed list with footnotes about those criticisms.
Q. Did any of your criticisms suggest that the $10.81 cost to dispense found by Myers and Stauffer

Page 296

was too high?
A. Not as an average. But again, for individual pharmacies it may be.
Q. And in fact your criticisms as you had expressed in June 2008 suggested that if anything the Myers and Stauffer cost of dispensing was too low, correct?
A. As an average.
Q. Yes.
A. But not for all pharmacies in California.
Q. You suggested that perhaps Myers and Stauffer's cost of dispensing was too low as an average, correct?
A. As an average or median or mean, yes.
Q. Now, Myers and Stauffer also determined what the average cost to acquire drugs was for pharmacies in California in 2007, at least for the thousand or so single-source drugs that they surveyed, correct?
A. They have an acquisition cost estimate, if that's what you mean by acquired drugs.
Q. And the acquisition cost estimate I think

Page 297

we already determined for single-source drugs was 79 percent of average wholesale price, correct?
A. The average average acquisition cost was that. Again, it's an average of averages for -- an average of the invoices for an NDC and an average of the averages across all those NDCs.
Q. And of the multiple-source drugs that Myers and Stauffer surveyed they determined that on average those multiple-source drugs were acquired at 63.6 percent of the average wholesale price?
A. That's what's represented in their conclusions. That's their average given their methodology.
Q. Do you have any reason to believe that Myers and Stauffer's average acquisition cost calculations are inaccurate?
A. I think there are issues one could raise about their methods. I think it's a useful number given the qualifications of how they did it. But again, it's an average. It's not a number that one could use in a reimbursement system.
Q. And Myers and Stauffer concluded that for

Page 330

would result in patients who do not receive the care that they need and will end up seeking alternative sources of care that may be less effective, more costly or both, right?

A. Based on the payments that are below the actual cost to the pharmacy and providing medications, yes.

Q. And you did that by calculating whether the revised payment with the 10 percent reduction would be below the pharmacy's total cost of dispensing the prescription, correct?

A. I did compare to their total cost of dispensing, their cost of dispensing plus their acquisition costs. And the total payment was below their total cost of acquiring the product and cost of dispensing.

Q. And if you turn to page romanette 2 -- it's the fourth page of the report, but it has romanette 2 on the bottom and it's in the executive summary -- and looking at the second paragraph of the executive summary page romanette 2, for the record, it reads "If the payment method sets the prescription payment

Page 331

amount below the actual cost for either drug product cost, cost of dispensing and related additional costs, or both, then problems with Medicare beneficiary access to pharmacy services will occur."

That is a true statement, isn't it?

A. I don't see where you're at in the document.

Q. Certainly. Romanette 2.

A. I'm on that page. Oh. No. I'm on page 4, I guess. That's why. Yes. I see that.

Q. Is that a true statement?

A. I believe the statement to be true, yes.

Q. And where you use Medicare did you mean Medicaid?

A. It may well be -- I probably should have used Medi-Cal, I think. And I think my word processor may have flipped that automatically.

Q. But regardless of whether it's Medicare, Medicaid or Medi-Cal, that notion is accurate across all federal health programs, correct?

MS. BROOKER: Objection, form.

A. Yes and no. First of all, this refers to

Page 332

paying below actual cost for various components and it refers to the policymaker having information that allows them to accurately determine what's below actual cost and having information that would allow them to have a policy that could be used on a broader reimbursement basis over time.

Q. This statement, this true statement, one sentence true statement, doesn't say anything at all about the value of or the quality of data that the provider has, correct?

MS. BROOKER: Objection, form.

A. This is a one sentence true statement that is encompassed by an entire report that gives the context under which that statement has truth. And I would say that the entire context of this document is necessary and you can't just take that statement by itself out of context.

Q. But you would agree with me as a general matter if the payment method that a healthcare program sets for prescription payments results in an amount that is below the cost of dispensing and related additional costs taken together plus the drug cost

Page 333

then you will see problems with access to pharmacy services?

MS. BROOKER: Objection, form.

A. I believe if pharmacies are paid below their cost for product and dispensing in aggregate over time in a program, they may choose not to participate in that program. I'm not aware, though, that Medicaid or Medicare policy either advocate paying pharmacies below their actual cost of dispensing or actual cost of ingredients.

So I don't believe that either Medicare or Medicaid in general have policies that intend to pay pharmacies below their actual cost.

Q. And then if you turn to page romanette 3, the very first paragraph, you define what a reasonable pharmacy payment consists of. And you say that it "is a payment that covers the drug ingredient cost plus the cost of dispensing plus a reasonable net profit." Is that an accurate statement of what a reasonable pharmacy payment is?

A. In the context of the entire report and how I describe that, it is. That's from the perspective

Page 334

of the pharmacy as a provider and as a person operating a private business. It's a reasonable statement from that perspective, yes.

Q. And in attempting to calculate what the cost is to dispense drugs for purposes of this June 2008 study you relied upon Myers and Stauffer's December 2007 report that we reviewed and that was marked as Exhibit 3, correct?

A. I examined that and used information from that as well as other studies that I also used and relied upon, studies conducted by the National Association of Chain Drug Stores, National Community Pharmacist's Association. So I didn't rely solely upon them. I did incorporate the information. I critiqued and commented on its appropriate use.

Q. If you look on page romanette 5, the last paragraph on this page, you refer to a cost of dispensing study that was recently performed in California for the Department of Health Services. There's no citation there, but you'll agree with me that that was the Myers and Stauffer report that you were referring to, right?

Page 335

A. Yes. And you're actually in the executive summary and if you look at the full report it does recognize and cite that. But again, it doesn't rely solely upon that. This is reporting their findings from their study.

Q. But then you take the findings from that study and adjust them to 2008 dollars in order to support the opinions that you express here, correct?

A. I used their numbers. Since their numbers were lower than other studies that I think perhaps are more accurate, I felt it was a conservative number. And I did -- yes, pharmacies' costs, just like other costs of businesses, do change over time. And I did adjust them using an inflation method that Myers and Stauffer themselves used to calculate their average across different businesses that had different fiscal years.

Q. And you concluded that 95 percent of California pharmacies have a cost to dispense that's greater than the $7.25 dispensing fee that Medi-Cal currently is providing to pharmacies, correct?

A. 95 percent have an average cost of

Page 336

dispensing that's greater than the Medi-Cal dispensing fee.

Q. Why do you use inflation adjusted dollars? I mean, why don't you use just current dollars?

A. Well, again, Myers and Stauffer themselves used it. And as I commented earlier, various businesses have changes in their prices other time and the cost of doing business. Pharmacists' salaries have gone up. Rents have gone up. I don't know. Maybe they've gone down now -- I don't know -- in the last six months. But costs do change over time. And Myers and Stauffer in that particular instance outlined what I thought was a reasonable method for adjusting.

In fact the data they collected on cost of dispensing from pharmacies was from pharmacies that had a variety of different fiscal years in terms of their business or tax records. And Myers and Stauffer had to adjust those to be in a common time period rather than a different time period. I used the same method they used to adjust those to a common time period to adjust them moving forward over time as

Page 337

well.

Q. So when you compare prices from one year to the next, do you typically use inflation adjusted dollars?

A. It depends on for what purpose we're comparing them. But if you're going to set a reimbursement rate based on an attempt to estimate actual cost of dispensing or actual acquisition cost, one would want to use -- if you didn't have actual cost or a new survey in each time period, which would be costly and perhaps not so feasible in all cases, then you need a method to make an adjustment for the time change in cost that might occur.

Q. If you would turn to page 8, please.

A. Regular 8?

Q. Yes, sir. Regular 8. In the third full paragraph leading into the block quote, beginning with "the total," you write "The total amount of fee for service payments to a pharmacy for a prescription must be taken into account including both the actual drug product cost payment and the reasonable dispensing fee payment." Why must you take into account the total

Page 338

fee for service payments to a pharmacy for a prescription, including the actual drug product cost payment and the reasonable dispensing fee payment?

A. Well, both will influence the business decision a pharmacy makes as to whether or not to accept or participate in a third party program. That's different than determining what the obligation of the payor is to do and what they choose to do given information that they know. In the paragraph just before that I do state what the CMS policy is with respect to estimated acquisition cost and that it clearly states that estimated acquisition cost is meant to be as close as feasible to the price generally and currently paid by a provider and that the states are therefore expected to set their ingredient cost levels at that rate.

Q. And then in the paragraph after the block quote, the second sentence, you write "At the same time that Medicaid payment policy is implemented to assure" --

A. I'm sorry. Where is it?

Q. I'm sorry. Page 8. Last paragraph. It's

Page 339

on the screen here.

A. Oh, you skipped the first sentence of that paragraph.

Q. Yes, sir. The second sentence after the footnote 27. Well, let's start with the first sentence. You state "Payment of the actual drug ingredient cost via an estimated acquisition cost for a drug product is 'the appropriate conceptual basis for the payment policy,'" correct?

A. That's the statement, yes.

Q. And that's the notion that you've been asserting in your report in this case and in your testimony here today, correct?

A. I believe that's an appropriate notion, yes.

Q. In this particular report, however, you go on and state in addition "At the same time that Medicaid payment policy is implemented to assure actual cost payment for the drug product, it is essential that the payment for the cost of dispensing, the pharmacy's overhead and profit and other costs also be adjusted to assure that actual costs and

Page 340

expenses are paid." Do you see that?

A. I see that, yes.

Q. It's that additional consideration stated in that sentence that you did not undertake in your analysis for this case, correct?

MS. BROOKER: Objection, form.

A. I was not asked to undertake that analysis and it doesn't -- isn't necessary for any of the opinions that I've adopted in this case. And this is in a different circumstance. This is with respect to what is the impact on the providers and the behavior of the providers. It's a different circumstance.

Q. And you weren't asked to determine what the payment would have been to providers between 1991 and 2001 to see their drug payments cut in the manner that Dr. Duggan suggests, did you?

MS. BROOKER: Objection, form.

A. Well, I wasn't asked to do the damages analysis. Dr. Duggan was. I do realize that it's not as simple as just if you cut the payment on drug ingredient cost you have to raise the cost of dispensing because the pharmacies for generic

Page 341

products, which is what we're talking about here, the pharmacies may have actually used a different generic product in the first place.

So I don't think you can directly connect those two in the way that I've done in this report and the way that is necessary for this report. I think they're very different issues and I don't think you can make that connection. And certainly a connection of that type wasn't necessary to underpin any of the opinions that I've offered in this case.

Q. This report didn't address the impact of using the cost or the payment to pharmacies that dispense these products?

A. What do you mean by "this report"?

Q. I'm sorry. Your June 2008 report in California did not address what the impact would be on pharmacies that dispense generic products?

A. My June 2008 --

MS. BROOKER: Objection, form.

A. My June 2008 report does address impact on providers. The report for the U.S. versus Abbott case I was not asked to and didn't address the impact on